



Food and Drug Administration
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October 15, 2014

AEGIS Regulatory Incorporated
% Ms. Susan Anthoney-De Wet
Medtek Lighting
2424 Dempster Drive
Coralville, Iowa 52241

Re: K134009

Trade/Device Name: UV Biotek Multi-Directional and UV Biotek Single
Panel (models 100B/80B/60B/40B)

Regulation Number: 21 CFR 878.4630

Regulation Name: Ultraviolet lamp for dermatologic disorders

Regulatory Class: Class II

Product Code: FTC

Dated: August 8, 2014

Received: September 15, 2014

Dear Ms. De Wet:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Binita S. Ashar -S

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Binita S. Ashar, M.D., M.B.A., F.A.C.S.

Director

Division of Surgical Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K134009

Device Name

UV BioteK Multi-Directional and UV BioteK Single Panel (models 100B/80B/60B/40B)

Indications for Use (Describe)

The UV BioteK Multi-Directional device is for individuals who require specific Ultraviolet radiation therapy for diagnosed skin disorders and is used for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I - VI).

The UV BioteK Single Panel Unit device models 100B/80B/60B/40B are for individuals who require specific Ultraviolet radiation therapy for diagnosed skin disorders and is used for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I - VI)

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

K 134009

Preparation Date: October 14, 2014

1. Submitter Information: AEGIS Regulatory, Inc. - Robert T. Wagner
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For Manufacturer: MedTek Lighting, Inc.
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3 Depot St.
Hudson Falls, NY 12839
Tel.: 518-747-3310

2. General Information:

- 2.1 Classification Name: FTC – Ultraviolet lamp for dermatologic disorders
- 2.2 Common/Usual Name: UV Biotek Multi-Directional and UV Biotek Single Panel
- 2.3 Proprietary Names: UV Biotek Multi-Directional and UV Biotek Single Panel models 100B/80B/60B/40B
- 2.4 Classification: Class II
- 2.5 Classification Number: 878.4630
- 2.6 Product Code: FTC

3. Device Description:

The UV Biotek Multi-Directional model is a phototherapy device, wall mounted with 3 lighting panels containing a total of 10 Philips TL100W/01 (narrowband UVB) or 10 Philips FS72T12/BL/HO/12 (wideband UVB) lamps. The center panel contains 6 lamps and the outer panels contain 2 lamps each, driven by standard electrical lighting systems at 120 Volts, producing 1000 Watts of primary UVB emissions within an enclosed metal (structure) and acrylic (exposure) housing, that is utilized at a the patient's home by prescription, and only with protective eyewear, as outlined in 21 CFR 892.6500. Cabinet dimensions: 85.5" high, 9" deep, 22.5" wide – when the door panels are closed. A digital AccuSafe control timer module is used to program exposure times and dosages.

The UV Biotek Single Panel device is a phototherapy device, wall mounted with a single lighting panel with an array of 4, 6, 8 or 10 Philips TL100W/01 (narrowband UVB) or Philips FS72T12/BL/HO/12 (wideband UVB) lamps, driven by standard electrical

lighting systems at 120 Volts, producing 400 to 1000 Watts of primary UVB emissions within an enclosed metal (structure) and acrylic (exposure) housing, that is utilized at the patient's home by prescription, and only with protective eyewear, as outlined in 21 CFR 892.6500.

Cabinet dimensions: 85.5" high, 5" deep, 22" wide – when door panels are closed. A digital AccuSafe control timer module is used to program exposure times and dosages.

There are 4 single panel models to choose from:

- The 100B model is one metal cabinet, housing (10) Philips TL100W/01 (narrowband UVB) or Philips FS72T12/BL/HO/12 (wideband UVB) lamps.
- The 80B model is one metal cabinet, housing (8) Philips TL100W/01 (narrowband UVB) or Philips FS72T12/BL/HO/12 (wideband UVB) lamps.
- The 60B model is one metal cabinet, housing (6) Philips TL100W/01 (narrowband UVB) or Philips FS72T12/BL/HO/12 (wideband UVB) lamps.
- The 40B model is one metal cabinet, housing (4) Philips TL100W/01 (narrowband UVB) or Philips FS72T12/BL/HO/12 (wideband UVB) lamps.

4. Intended Use:

The UV Biotek Multi-Directional is for individuals who require specific Ultraviolet radiation therapy for diagnosed skin disorders and is used for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I - VI)

The UV Biotek Single Panel Unit models 100B/80B/60B/40B are for individuals who require specific Ultraviolet radiation therapy for diagnosed skin disorders and is used for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I - VI)

5. Predicate Device:

These devices are substantially equivalent to the following predicate device, which is currently in safe and effective commerce:

1. K111049- UV Biotek Mobile/Versa Lite (Medtek Lighting)

Predicate Chart

Device	UVBioTek Multi Directional	UVBioTek Single Panel 100B/80B/60B/40B	UV Biotek Mobile/Versa Lite
Company	MedTek Lighting	MedTek Lighting	Medtek Lighting
"K" number	This submission	This submission	K111049 (predicate device)
Indications for use	For the treatment of psoriasis, vitiligo and atropic dermatitis (eczema) on all skin types (I-VI)	For the treatment of psoriasis, vitiligo and atropic dermatitis (eczema) on all skin types (I-VI)	For the treatment of psoriasis, vitiligo and atropic dermatitis (eczema) on all skin types (I-VI)
Power	120V - 60Hz	120V - 60Hz	120V-60Hz
Treatment Spot Size	Full Body	Full Body	Full Body, spot, scalp, hand, foot
Housing Materials	Steel, acrylic safety shield, UV lamps, timer, goggles	Steel, acrylic safety shield, UV lamps, timer, goggles	Steel, acrylic safety shield, UV lamps, timer, goggles
Energy Source	12V Power Adapter	12V Power Adapter	12V Power Adapter
Number of Lamps	10 Narrowband UVB	10, 8, 6, or 4 NB UVB	14, 8, 6, or 2 NB UVB

Model Number Wattage	Philips TL100W/01 Lamp Wattage 100W	Philips TL100W/01 Lamp Wattage 100W	Philips TL20W/01 Lamp Wattage 20W
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6. Substantial Equivalence to Predicate Device:

These devices have the same technological characteristics as the cited predicate device. Both devices use the same design, material, and energy source as the cited predicate device. Minor technological differences between the proposed devices and the predicate device do not affect safety or efficacy.

After an analysis of the safety, indications, intended uses, performance features, design materials, chemical composition, energy source, power output, technological properties, treatment areas, treatment regimes and methods of operation, the manufacturer believes that no significant differences exist between the device and the predicate device listed in section 5 of this summary.

Therefore substantial equivalency is requested.

7. Performance Standards:

These devices have been tested under and are in compliance with performance standards that have been established for such devices under Section 878 of the Federal Food, Drug, and Cosmetics Act. All electrical and radiological products made by the applicant have been OSHA/NRTL listed, and have received constituent marks and are found to be in conformance with EN/IEC 60601-1 Electrical Safety and EN/IEC 60601-1-2:2007 EMC.

Specific performance testing was done on these devices to measure irradiance and for comparison to the predicate device. These measurements were used to reach the recommended dose (mJ/cm²) for the treatment of psoriasis found in published scientific literature.

Conclusion

After an analysis of the safety, indications, intended uses, performance features, design materials, chemical composition, energy source, power output, technological properties, treatment areas, treatment regimes and methods of operation, the manufacturer believes that no significant differences exist between the device and the predicate device listed in section 5 of this summary.

Therefore substantial equivalency is requested.